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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,400	08/26/2003	William E. Bunney JR.	020885-000720US	6108

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EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,400	BUNNEY ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a method of determining whether a subject is predisposed to a mental disorder, classified in class 424, subclass 9.1.

II. Claims 13-22, drawn to method of identifying compounds for the treatment of a mental disorder comprising determining the functional effect on the polypeptide of SEQ ID NO: 1 or 3, classified in class435, subclass 7.2.

III. Claims 23-31 drawn to a method of identifying compounds that for the treatment of a mental disorder comprising determining the effect on expression levels of the polypeptide of SEQ ID NO: 1 or 3, classified in class 435, subclass 7.2.

IV. Claims 32-40 to a method of treating a mental disorder comprising administration of the compound discovered via the inventions of Groups II or III, classified in class 514, subclass 1.

V. Claims 41-45 drawn to a method of treating a mental illness comprising administration of a polypeptide of SEQ ID NO: 1 or 3, classified in class 514, subclass 2.

VI. Claims 45-50, drawn to administering a therapeutic nucleic acid that hybridizes to the nucleic acid encoding the polypeptides of SEQ ID NO: 1 or 3, classified in class 514, subclass 44.

2. Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Groups I and IV-VI are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention group I is a method of determining whether a subject has a mental illness (i.e., it's a diagnostic test) and requires testing for the presence of a protein or nucleic acid. The inventions of groups IV-VI are all methods of treating by administration. Therefore the methods have different goals and steps and use different materials. Therefore a search and examination of the methods of group I with the methods of groups IV-VI would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

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3. Groups IV-VI are each directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention group IV is a method of treating by administering a compound, whereas groups V and VI are methods of treating by administering polypeptides (V) or nucleic acids (VI). Therefore each method uses physically and functionally different products for treatment. M Therefore a search and examination of the methods of groups IV-VI would constitute an undue burden, since the searches are entirely different and not coextensive, and the subject matter divergent.

4. Groups I and II-III are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention group I is a method of determining whether a subject has a mental illness (i.e., it's a diagnostic test) and requires testing for the presence of a protein of nucleic acid. The inventions of groups II and III are all methods of identifying compounds. Therefore the methods have different goals and steps and use different materials. Therefore a search and examination of the methods of group I with the methods of groups II-III would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

5. Groups II-III and IV-VI are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention groups II-III are method of identifying compounds that affect activity (II) or expression of a protein (III). The methods of groups IV-VI are all directed to treating a mental illness or disorder by administering a compound (IV), a polypeptide (V), or a nucleic acid (VI).

Therefore the methods have different goals and steps and use different materials. Therefore a search and examination of the methods of group II-III with the methods of groups IV-VI would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

6. Groups II and III are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Invention group II is a method of identifying compounds that modify the *activity* of the polypeptides of SEQ ID NO: 1 or 3, whereas group III is a method of identifying compounds that modulate expression of the polypeptides of SEQ ID NO: 1 or 3. The methods have different goals and different steps. Therefore a search and examination of the methods of group II with the method of group III would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Election of Species

7. Should applicant choose ANY one of groups I-VI, further elections of species are required. This application contains claims directed to the following patentably distinct species of the claimed invention: SEQ ID NO: 1, or 3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, "a polypeptide encoded by a nucleic acid" is generic. The methods of group I-VI can use either SEQ ID NO: 1 or 3, which are

physically distinct from each other and not required for on another. These are unique sequences encoding proteins with patentably different polypeptide sequences. Therefore the searches are not coextensive and would represent a serious burden on the examiner.

8. Should applicant choose the method of group I, further elections of species are required. This application contains claims directed to the following patentably distinct species of the claimed invention: an antibody, or a nucleic acid.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, "a reagent that selectively associates with a polynucleotide of polypeptide" is generic. The method of group I can use either a nucleic acid or an antibody, which are physically distinct from each other and not required for on another. Therefore the searches are not coextensive and would represent a serious burden on the examiner.

9. Should applicant choose ANY of groups I-VI, a further election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: bipolar illness, major depression, or schizophrenia.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, "mental illness" is generic. The method of group I is a method of diagnosing bipolar illness, major depression, or schizophrenia. Because the diseases are distinct from eachother and consist of non-overlapping

patient populations, methods of determining predisposition to each distinct disease are patentably distinct. Therefore the searches are not coextensive and would represent a serious burden on the examiner.

10. Should applicant choose the method of groups II, a further election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: an in vitro method, a method wherein the polypeptide is expressed in a cell, and a method wherein the compound is administered to an animal.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, "contacting the compound with a polypeptide" is generic. The method of group II is a method of identifying compounds that affect the activity of the polypeptide of SEQ ID NO: 1 or 3 using an in vitro method, SEQ ID NO: 1or 3 expressed in a cell, or in an animal. These methods are physically and functionally distinct because they require different products and measure entirely different things. Therefore the searches are not coextensive and would represent a serious burden on the examiner.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
8/21/05

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER